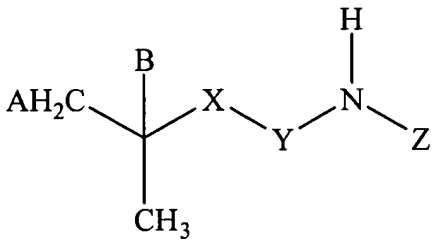
Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims

Claims 1-34 (canceled)

Claim 35 (currently amended): An oral sustained-release pharmaceutical composition comprising a core matrix comprising (1) a therapeutically effective amount of an active compound and (2) a gelling agent, wherein the amount of said active compound ~~and gelling agent together is~~ represents about ~~30-90% w/w~~ 40-70% by weight of the composition, and wherein said active compound is selected from the group consisting of: isovaleric acid, a pharmaceutically acceptable salt of isovaleric acid, a pharmaceutically acceptable ester of isovaleric acid, a compound having the structure:



wherein A = H, CH_3 or OH,

B = H, OH, or CH_3,

X = CH_2, $CHCH_3$, $C(CH_3)_2$, -O-, CH(OH)-, or $-CH_2O-$,

Y = -CO-, or $-SO_2-$, and

Z = H, CH_2CO_2H, or CH_2CONH_2,

and a compound selected from the group consisting of isovaleramide, 2-methylisovaleramide, 3-methylisovaleramide, 2,2-dimethylisovaleramide, 2,3-dimethylisovaleramide, 4-methylisovaleramide, 2,4-dimethylisovaleramide, 3,4-dimethylisovaleramide, 2,2,4-

trimethylisovaleramide, 3-hydroxyisovaleramide, 4-hydroxyisovaleramide, 4-hydroxy-3-methyl-isovaleramide, 2-hydroxyisovaleramide, N-(2-acetamido)isovaleramide, 2-methyl-1-propyl sulfonamide, 1-methylethyl sulfamate, 2-methyl-1-propyl sulfamate, isopropyl carbamate, and isobutylcarbamate.

Claim 36 (canceled)

Claim 37 (previously presented): A composition according to claim 35, wherein said composition releases said active compound at a rate sufficient to maintain a therapeutically effective serum concentration of said active compound for at least 8 hours.

Claim 38 (previously presented): A composition according to claim 35, wherein said composition releases said active compound at a rate sufficient to maintain a therapeutically effective serum concentration of said active compound for at least 12 hours.

Claim 39 (previously presented): A composition according to claim 35, wherein said gelling agent comprises xanthan gum.

Claim 40 (previously presented): A composition according to claim 35, wherein said composition has a film-coating that retards access of liquids to the active compound and/or retards release of the active compound through the film-coating.

Claim 41 (previously presented): A composition according to claim 35, further comprising one or more excipients.

Claim 42 (previously presented): A composition according to claim 35, wherein said active compound is isovaleramide.

Claim 43 (cancelled)

Claim 44 (previously presented): A composition according to claim 40, wherein said film coating comprises a polymeric coating material.

Claim 45 (previously presented): A composition according to claim 44, wherein said polymeric coating material comprises a mixture of ethyl cellulose and hydroxypropyl methylcellulose.

Claim 46 (previously presented): A composition according to claim 44, wherein said polymeric coating material further comprises a plasticizer.

Claim 47 (previously presented): A composition according to claim 35, wherein the composition is in the form of a tablet, capsule, or multiparticulate composition.

Claim 48 (currently amended): A process for preparing an oral sustained-release pharmaceutical composition comprising a core matrix comprising (1) a therapeutically effective

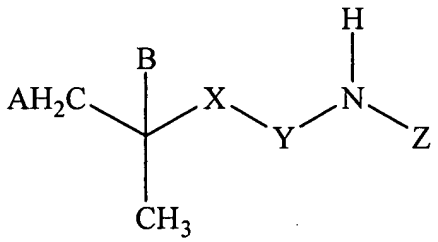
amount of an active compound, (2) a gelling agent, and (3) optionally one or more substances that further retards the release of the active compound, comprising:

(a) mixing together a therapeutically effective amount of an active compound with a gelling agent and optionally one or more substances that further retards the release of the active compound, and

(b) compressing or extruding said active compound, gelling agent, and optional substances that act to sustain release of the active compound,

wherein the amount of said active compound ~~and gelling agent together is~~ represents about ~~30-90% w/w~~ 40-70% by weight of the composition, and

wherein the active compound is selected from the group consisting of: isovaleric acid, a pharmaceutically acceptable salt of isovaleric acid, a pharmaceutically acceptable ester of isovaleric acid, an active compound having the structure:



wherein A = H, CH_3 or OH,

B = H, OH, or CH_3,

X = CH_2, $CHCH_3$, $C(CH_3)_2$, -O-, CH(OH)-, or $-CH_2O-$,

Y = -CO-, or $-SO_2-$, and

Z = H, CH_2CO_2H, or CH_2CONH_2,

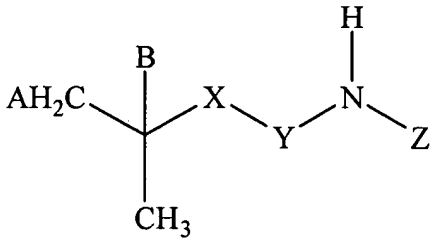
and a compound selected from the group consisting of isovaleramide, 2-methylisovaleramide, 3-methylisovaleramide, 2,2-dimethylisovaleramide, 2,3-dimethylisovaleramide, 4-methylisovaleramide, 2,4-dimethylisovaleramide, 3,4-dimethylisovaleramide, 2,2,4-

trimethylisovaleramide, 3-hydroxyisovaleramide, 4-hydroxyisovaleramide, 4-hydroxy-3-methyl-isovaleramide, 2-hydroxyisovaleramide, N-(2-acetamido)isovaleramide, 2-methyl-1-propyl sulfonamide, 1-methylethyl sulfamate, 2-methyl-1-propyl sulfamate, isopropyl carbamate, and isobutylcarbamate.

Claim 49 (previously presented): A process according to claim 48, wherein said gelling agent comprises xanthan gum.

Claim 50 (previously presented): A process according to claim 48, further comprising the step of coating the core matrix with a polymer solution to form a film-coating.

Claim 51 (currently amended): A method of treating a pathology that is ameliorated by a modulation of CNS activity, wherein said pathology is selected from the group consisting of convulsions, spasticity, affective mood disorder, neuropathic pain syndrome, headache, restlessness syndrome, movement disorder substance abuse/craving, and cerebral trauma, comprising administering to a patient suffering from said pathology an oral sustained-release pharmaceutical composition comprising a core matrix comprising (1) a therapeutically effective amount of an active compound and (2) a gelling agent, wherein the amount of said active compound ~~and gelling agent together is~~ represents about ~~30-90% w/w~~ 40-70% by weight of the composition, and wherein said active compound is selected from the group consisting of: isovaleric acid, a pharmaceutically acceptable salt of isovaleric acid, a pharmaceutically acceptable ester of isovaleric acid, isovaleramide, a compound having the structure:



wherein A = H, CH_3 or OH,

B = H, OH, or CH_3,

X = CH_2, $CHCH_3$, $C(CH_3)_2$, -O-, CH(OH)-, or $-CH_2O-$,

Y = -CO-, or $-SO_2-$, and

Z = H, CH_2CO_2H, or CH_2CONH_2,

and a compound selected from the group consisting of 2-methylisovaleramide, 3-methylisovaleramide, 2,2-dimethylisovaleramide, 2,3-dimethylisovaleramide, 4-methylisovaleramide, 2,4-dimethylisovaleramide, 3,4-dimethylisovaleramide, 2,2,4-trimethylisovaleramide, 3-hydroxyisovaleramide, 4-hydroxyisovaleramide, 4-hydroxy-3-methyl-isovaleramide, 2-hydroxyisovaleramide, N-(2-acetamido)isovaleramide, 2-methyl-1-propyl sulfonamide, 1-methylethyl sulfamate, 2-methyl-1-propyl sulfamate, isopropyl carbamate, and isobutylcarbamate,

with the proviso that the treated pathology is not convulsions when the compound is 3-methylisovaleramide, isopropyl carbamate, or isobutyl carbamate.

Claim 52 (previously presented): A method according to claim 51, wherein said sustained-release pharmaceutical composition is in tablet form and the tablet contains a therapeutically effective unit dose of the active compound.

Claim 53 (previously presented): A method according to claim 51, wherein said sustained-release pharmaceutical composition is a multiparticulate composition and the multiparticulate composition contains a therapeutically effective unit dose of the active compound.

Claim 54 (previously presented): A composition according to claim 51, wherein said gelling agent comprises xanthan gum.

Claim 55 (previously presented): A method according to claim 54 wherein said composition further comprises a film-coating comprising a polymeric coating material.

Claim 56 (canceled)

Claim 57 (previously presented): A method according to claim 51, wherein said active compound is isovaleramide.

Claims 58-59 (canceled)